Alaska Section of Epidemiology (SOE) Guidance for Coronavirus Disease 2019 (COVID-19) Testing in Alaska May 6, 2021

Key Points

- Providers must report laboratory-confirmed cases of COVID-19 to SOE via fax (907-563-7868)
 using the <u>standard Infectious Disease report form</u> or via electronic means. The reporting hotline
 has been discontinued.
- SOE staff can be reached for consultation at 907-269-8000 or 800-478-0084 (after-hours).
- The <u>Alaska State Public Health Laboratories</u> in Anchorage (ASPHL) and Fairbanks (ASVL) are running specimens 7 days a week at both facilities. STAT testing is generally not being offered. Specimens must be submitted with a <u>COVID Test Request form</u>.
- Anyone with symptoms who is being tested for COVID-19 should be informed to act as if they have COVID-19 until a result comes back. SOE guidance on what outpatients should do if they have COVID-19 or if a COVID-19 test is pending is available here.

Test Anybody in Alaska Who Is Experiencing Symptoms of COVID-19

- Symptomatic persons should be tested regardless of vaccination status.
- Symptoms of COVID-19 may include any of the following: fever, cough, shortness of breath, difficulty breathing, chills, decreased appetite, diminished sense of taste or smell, diarrhea, fatigue, headache, muscle/joint aches, nausea, rash, rigors, runny nose, sore throat, or sputum production.
- Positive antigen or molecular test results that occur within 3 months of each other are not
 generally considered a second infection. However, a positive test in a prior case with onset of new
 symptoms should not necessarily be ruled out as a residual infection. Consult with SOE regarding
 the possibility for second cases.

Testing for Asymptomatic Unvaccinated Persons

- There may be circumstances whereby an asymptomatic unvaccinated person seeks testing or is recommended to be tested. Requirements for routine screening may also be present in some venues. Such circumstances could include:
 - o In accordance with State Health Advisories or as required by local communities
 - o Upon admission to a health care facility based on facility policy
 - Patients who may be at higher risk of spreading COVID-19, including those who require
 aerosolizing procedures such as suctioning, intubation, or breathing treatments or delivery
 - Patients at higher risk for complications associated with intubation if COVID positive
 - o Residents and staff living or working in healthcare settings (see DHSS Guidance for congregate residential settings, and skilled nursing homes). On 4/27/21, CDC quarantine guidance changed for those working in healthcare settings based on vaccination status. Questions specific to these settings can be directed to the Assisted Living Facility (ALF) hotline (833-603-2537).
 - o Workers in non-healthcare congregate settings (see Table 1 following an exposure).
- Note that any asymptomatic person who has had a positive antigen or molecular test in the prior 90 days should NOT be re-tested.

Testing for Asymptomatic Vaccinated Persons

- As of 4/27/21, <u>CDC currently recommends that asymptomatic vaccinated persons are tested ONLY under certain circumstances such as for work or in congregate settings.</u> Testing may be indicated, regardless of vaccination status, following an exposure (Table 1).
- SOE and ASVL are particularly interested in sequencing specimens associated with "vaccine-

breakthrough" cases. To date, many specimens have not been able to be sequenced suggesting a low level of virus was present. For this reason, we recommend that these asymptomatic individuals consider the option to shorten isolation by obtaining serial negative tests separated by 24 hours.

Table 1. Testing and quarantine recommendations for persons, outside of a healthcare setting, exposed to SARS-CoV-2, by vaccination status¹

| | Quarantine following exposure | Testing following exposure ² | | | | | |
|---|---|---|--|--|--|--|--|
| Symptomatic persons | | | | | | | |
| Fully vaccinated ³ | Until negative test result and symptoms resolve | Recommended | | | | | |
| Unvaccinated or partially vaccinated persons | Yes ⁴ | Recommended | | | | | |
| Asymptomatic persons who reside in a non-healthcare congregate setting | | | | | | | |
| Unvaccinated or partially vaccinated persons | Yes ⁴ | Recommended | | | | | |
| Fully vaccinated ² | No | Recommended | | | | | |
| Asymptomatic persons who do not reside in a non-healthcare congregate living facility but work in a non-healthcare congregate setting or high-density workplace | | | | | | | |
| Unvaccinated or partially vaccinated persons | Yes ⁴ | Recommended | | | | | |
| Fully vaccinated ³ | No ⁵ | Recommended | | | | | |
| Asymptomatic persons who do not reside in a non-healthcare congregate living facility nor work in a | | | | | | | |
| non-healthcare congregate setting or high-density workplace | | | | | | | |
| Unvaccinated or partially vaccinated persons | Yes ⁴ | Recommended | | | | | |
| Fully vaccinated ³ | No | No | | | | | |

¹This guidance does not apply to those who work or live at a seafood processing facility, please find specific guidance for these individuals <u>here</u>.

Discontinuation of Isolation and Precautions

- Persons diagnosed with COVID-19 illness may discontinue isolation 10 days after symptom onset if
 their fever has been resolved for at least 24 hours (without the use of fever-reducing medications)
 and other symptoms are resolving.
 - A limited number of persons with severe illness may produce replication-competent virus beyond 10 days that may warrant extending duration of the isolation and precautions for up to 20 days after symptom onset; consider consultation with infection control experts and infectious disease physicians.
- Asymptomatic persons who test positive for SARS-CoV-2 infection via a <u>molecular</u> test may discontinue isolation 10 days after the specimen collection date of their first positive diagnostic test.
 - o However, asymptomatic persons may discontinue isolation <10 days after the specimen collection date of their first positive test if they have two subsequent negative molecular tests obtained at least 24 hours apart. If at any point clinically compatible symptoms develop, the patient should be placed into isolation and retested.
- For asymptomatic persons who test positive for SARS-CoV-2 infection via an <u>antigen</u> test, follow the antigen testing algorithm on page 4 below.

²Regardless of vaccine status, persons who have tested positive for SARS-CoV-2 in the past 90 days should not be tested if asymptomatic. If they are symptomatic, consultation with a physician is recommended. ³Fully vaccinated means ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.

⁴See Table 2 and its accompanying notes for quarantine options and considerations.

⁵Work exclusion may be still be required; persons should confirm the company policy with their employer.

Table 2. Options to reduce quarantine period for close contacts

| | Option 1 Test | Option 2 Time | | |
|--|---|------------------------|--|--|
| | 7-day Quarantine + Test | 10-day Quarantine | | |
| What type of test is required and when should it be obtained? | Molecular or antigen test; specimen must be collected <48 hours before the time of planned quarantine discontinuation (i.e., on day 6 or 7 of quarantine) | No Test Required | | |
| Can quarantine be further shortened with a negative test result? | No | No | | |
| When is the earliest that a person can be released from quarantine and go back to work or school? | 8 days after exposure with a negative test result | 11 days after exposure | | |
| What should patients do if they haven't gotten their test result back before the time of planned quarantine discontinuation? | Remain in quarantine until they get a negative test result or 10 days have passed, whichever is earlier (release on day 11) | No Test Required | | |
| Estimated residual post- quarantine transmission risk | 5% (upper limit: 12%) | 1% (upper limit: 10%) | | |
| What added precautions should people take after being released from quarantine under Option 1 or 2? | Take extra precautions until 14 days after exposure: watch for symptoms, wear a mask when in public areas, avoid crowds, maintain 6-foot distance from others, wash hands frequently, avoid any contact with high-risk persons, discuss with employer whether it is safe to return to work. | | | |

Notes:

- 1. The above options are only for contacts who have remained asymptomatic for the entire duration of their quarantine. Anyone who develops symptoms within 14 days of an exposure (regardless of whether or not they remain in quarantine) should immediately self-isolate and seek testing.
- 2. Persons can continue to be quarantined for 14 days per existing CDC recommendations; this option maximally reduces the risk of post-quarantine transmission and is the strategy with the greatest collective experience at present.
- 3. Due to the added risk of transmission associated with reduced quarantine periods, a full 14-day quarantine period is recommended for persons in certain high-risk residential settings, such as long-term care facility residents and correctional facility inmates. The full 14-day quarantine period is also recommended for unvaccinated workers in communal living and crowded work settings (e.g., dormitories, mining operations). All persons should consult with their employer for guidance.
- 4. Local community leadership (e.g., city mayor or Incident Command) may decide to continue a 14-day quarantine for residents of their communities, based on local conditions and needs. Prior to making this decision, community leadership should reach out to the Alaska Section of Public Health Nursing or the Section of Epidemiology to assure coordination.

Facilities with Their Own COVID-19 Molecular Laboratory Testing Capacity

- Providers must report laboratory-confirmed cases of COVID-19 to SOE via fax using the <u>standard Infectious Disease report form</u> or via electronic means.
 - o All results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds, submission of a standard format CSV via SFTP, or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) at SOE to inform us about how your facility will report.
- On 9/17/20, FDA issued an <u>amendment</u> for the Abbott ID NOW COVID-19 assay and its_

Instructions for Use. Changes include:

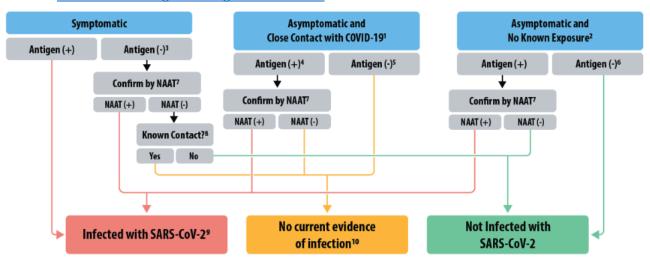
- o The assay is intended for detection from individuals within the first 7 days of symptom onset.
- o For best performance, it is highly recommended the test swab is placed in a clean, unused tube, capped tightly, and stored at room temperature for up to 1 hour prior to testing. If greater than a 1-hour delay occurs, dispose of sample and re-test the individual.
- o Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, patients should be re-swabbed and tested with a higher sensitivity molecular test (e.g., RT-PCR or Cepheid).
- o Positive results from symptomatic individuals obtained by the provider do <u>not</u> need to be confirmed by the ASPHL or ASVL. If they want to confirm for some reason, they must collect a new specimen in the appropriate transport media and send to ASPHL or ASVL.

Molecular Diagnostic Testing Accuracy

- The accuracy of SARS-CoV-2 molecular diagnostic tests is variable.
- Their specificity is generally considered to be excellent (>99%).
- Their sensitivity depends on the type and quality of the specimen obtained, when the patient
 was tested during the course of their infection, the technical ability of the person performing the
 test, and the performance characteristics of the specific assay.

Antigen Testing

• In December 2020, CDC released the following antigen testing algorithm in their <u>Interim</u> <u>Guidance for Antigen Testing for SARS-CoV-2</u>:



Technical Notes

- 1. Single, multiple, or continuous known exposure to a person with COVID-19 within the last 14 days; perform NAAT first if short turnaround time is available, if person cannot be effectively and safely quarantined, or if there are barriers to possible confirmatory testing
- 2. No known exposure to a person with COVID-19 within the last 14 days
- 3. If a symptomatic person has a low likelihood of SARS-CoV-2 infection, clinical discretion should determine if this negative antiqen test result requires confirmatory testing
- 4. In instances of higher pretest probability, such as high incidence of infection in the community, clinical discretion should determine if this positive antigen result requires confirmation
- 5. In certain settings, serial antigen testing could be considered for those with a negative antigen test result; serial testing may not require confirmation of negative results. The role of a negative antigen test result in ending quarantine depends upon when it is performed in the quarantine period. See CDC's Options to Reduce Quarantine for guidance on use of antigen testing for this

- purpose and when a negative antigen test result indicates not infected with SARS-CoV-2.
- 6. If prevalence of infection is not low in the community, clinical discretion should consider whether this negative antigen result requires confirmation
- 7. Nucleic acid amplification test; confirm within 48 hours using a NAAT, such as RT-PCR, that has been evaluated against FDA's reference panel for analytical sensitivity
- 8. Known exposure to a person with COVID-19 within the last 14 days; if unsure, clinical discretion should determine whether isolation is necessary
- 9. Isolation is necessary. See CDC's guidance for <u>Isolation</u>
- 10. Quarantine is necessary. See CDC's guidance for <u>Quarantine</u>; clinical discretion should determine if and when additional testing is necessary
- Tests that identify SARS-CoV-2 antigen are on the market and the <u>FDA has issued emergency</u> use authorizations for some of these tests.
- The main advantages of these tests are their rapid turn-around time and high specificity. The main disadvantage is lower sensitivity than molecular diagnostic tests.
- As with molecular testing, providers must report laboratory-confirmed cases of COVID-19 to SOE via fax using the <u>standard Infectious Disease report form</u> or via electronic means. In addition, all results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds, submission of a standard format csv via SFTP, or fax (907-563-7868). Please email Megan Tompkins (<u>megan.tompkins@alaska.gov</u>) to inform us about how your facility will report.
- On 8/5/20, <u>CSTE updated the case definition for COVID-19</u>. Cases with positive results via antigen testing are classified as "probable." The public health response (i.e., case investigation and contact tracing) is the same for these cases as for "confirmed" cases (i.e., those with positive results via molecular testing methods).

Specimen Type and Priority (based on CDC Guidance)

- FDA guidance on swabs and specimen transport media is available here.
- Please refer to the Table below to determine the appropriate swabs to use for testing.

| Swab Type | NP | OP | Mid-turbinate | Nasal |
|---------------------------------------|-----|-----|---------------|-------|
| Nasopharyngeal swab with tips made of | Yes | Yes | Yes | Yes |
| polyester, rayon, or flocked nylon | | | | |
| Flocked tapered swab | No | No | Yes | Yes |
| Flocked or spun polyester swab | No | No | Yes | Yes |
| 3D printed swabs | Yes | Yes | Yes | Yes |
| Cotton | No | No | No | No |
| Calcium alginate | No | No | No | No |
| Wood or metal (non-aluminum) shaft | No | No | No | No |
| Aluminum shaft | Yes | Yes | Yes | Yes |

- All swabs should be placed in a transport tube containing either viral/universal transport medium, Amies transport medium, sterile RNase-free saline or phosphate buffered saline (PBS).
- NOTE: Swab samples for testing on the Abbott ID NOW instrument should be placed directly into the instrument for testing. They should not be placed in any other media as this can reduce the sensitivity of the test through dilution, which can potentially lead to false negative result.
- An NP collection guidance video is available <u>here</u>. A self-collection guidance video is available <u>here</u>.
- Testing may be performed on lower respiratory tract specimens, if available.
 - For patients who develop a productive cough, sputum should be collected and tested for SARS- CoV-2. The induction of sputum is not recommended.

- When it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.
- Maintain <u>proper infection control</u> when collecting specimens. See <u>Biosafety FAQs</u> for handling and processing specimens from suspected case patients.

Sequencing and Variant Detection

- All positive specimens collected in UTM/VTM should be submitted to ASVL for sequencing. (This
 includes specimens tested on the Cepheid GeneXpert and most high-throughput assays.) Recollection is not necessary; submit the remainder of the specimen.
 - Even if ASVL is unable to attempt sequencing of the specimen at the time it is received, the specimen will be stored in ASVL's positive specimen repository. This repository is valuable for subsequent epidemiological investigations, such as investigating potential re-infections and variant of concern source investigations.
 - If a facility has an alternative approach for sequencing its positive specimens (e.g., in-house sequencing capacity), please notify SOE so that processes can be established to link sequence data to epidemiological data.
- Priority specimens for sequencing include those from patients that have recently traveled outside
 of Alaska, are in rural Alaska, have been vaccinated, are suspected to have been re-infected, are
 part of outbreaks, or are in locations not experiencing significant community transmission.
- Specimens that are not collected in UTM/VTM cannot be sequenced (this includes most specimens tested on rapid assays such as the Abbott ID NOW and Binax NOW). To perform sequencing, another specimen would need to be collected from the patient and stored in UTM/VTM.
 - o While *not* required, diagnostic specimen re-collection and submission for sequencing is <u>strongly</u> <u>encouraged</u> for patients in any of the priority categories listed above.
- Send positive specimens as Category B samples to ASVL in Fairbanks, per shipping instructions.
 - o Positives can be batched and submitted once per week.
 - o ASVL can provide swabs and UTM/VTM to facilities. Keep frozen until shipping and send with ice packs around the samples in the package.
 - o Refer to the "<u>Guide for Healthcare Providers</u>" for additional details; Table 2 in that document provides detailed information about whether sequencing from a particular assay requires recollection.
 - o For more information about sequencing SARS-CoV-2 in Alaska, click <u>here</u>.
 - o For more information about COVID-19 variants, click here.
 - o For the most recent Alaska SARS-CoV-2 genomics report, click here.

Serologic Testing

- Refer to the Infectious Diseases Society of America (IDSA) Guidelines on the Diagnosis of COVID-19
 regarding serologic testing here. CDC's interim guidelines on antibody testing are here.
- Serological tests should not be used as an alternative to molecular or antigen tests for the diagnosis of COVID-19 in symptomatic patients. Regardless of their serologic results, symptomatic patients should be tested for COVID-19 via molecular or antigen methods.
 - o Interpreting positive serologic test results can be particularly difficult in persons who did not have a prior clinically compatible illness or a positive RT-PCR test for COVID-19. We do not yet have a good understanding of the specificity of the various serologic assays for COVID-19.
 - o Cross-reactivity with other circulating coronaviruses may lead to a false-positive result.
- Even if a person does have antibodies to SARS-CoV-2, whether these antibodies confer immunity is unknown. Therefore, IDSA recommends that antibody tests not be used to make decisions about whether personal protective equipment is needed.
- CDC does not recommend antibody testing prior to vaccination, nor does CDC recommend

- antibody testing after vaccination. One reason why antibody testing is not recommended following vaccination is that cell-mediated immunity may contribute to vaccine-induced immunity, and cell-mediated immunity is not assessed by antibody assays.
- All SARS-CoV-2 serologic test results (i.e., positive, negative, indeterminate, etc.) must be reported via either integration into existing electronic laboratory reporting (ELR) data feeds, submission of a standard format csv via SFTP, or fax (907-563-7868). Please email Megan Tompkins (megan.tompkins@alaska.gov) to inform us about how your facility will report.

At-Home Testing

- At-home collection kits and tests are available either by prescription or over-the-counter in a pharmacy or retail store without a prescription.
- Currently available at-home tests look for current infection.
- Patients should communicate positive test results to their healthcare provider.
- Patients testing positive should be advised to get a confirmatory test from a certified testing facility.
- More information about at-home testing is available here.

Note: Because the sensitivity of all COVID-19 tests is <100%, a negative test result does not rule out infection. This is a particularly important point to consider when caring for patients with a clinically compatible illness and known contact to a confirmed case.

Please check the <u>DHSS COVID-19 website</u> and <u>CDC's COVID-19 website</u> frequently for updates.